

K090127 1/2

MAY - 1 2009

510(k) Summary as required by section 807.92(c)

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: April 8, 2009
Applicant: Solana Surgical, LLC
1828 Bailey Drive
Oceanside, CA 92056

Common Name: Toe joint, phalangeal (hemi-toe) prosthesis
Device Trade Name: Metatarsal Decompression Implant
Toe joint phalangeal (hemi-toe) polymer prosthesis.

Device Classification Name:

Class II

Device Classification:

Reviewing Panel: Orthopedic
Regulation Number: 888.3730
Product Code: KWD
Predicate Device: K070052 Vilex, Met-Head, Resurfacing
Hemi-Arthroplasty Implant
K031859 Arthrosurface, CAP Great Toe
Resurfacing Hemi-Arthroplasty Implant
Registration Number: Pending
Owner Operator Number: Pending

Device Description:

The Solana Surgical Implant is a one-piece device made of Cobalt Chromium, intended to replace the articulating surface of the first metatarsal at the metatarsalphalangeal (MTP) joint. The implant is available in a range of sizes to match the geometry of the metatarsal head. Design features include an articulating surface and a stem which extends proximally in the intramedullary canal of the metatarsal. The design of the Solana Surgical implant is similar to the predicate devices. No new materials or processes are used in the development of this implant.

Indications for Use:

The Solana Surgical LLC, Metatarsal Decompression Implant is intended for use as a hemi-arthroplasty implant for the first metatarsophalangeal joint, for the treatment of degenerative and post-traumatic arthritis, hallux valgus, hallux rigidus, and an unstable or painful metatarsophalangeal (MTP) joint.

The device is intended for single use to be used with bone cement.

Comparison to Predicate Device:

Similarities of the Solana Surgical device to its predicates include these devices being: intended for single use only, intended for surgical implantation longer than 30 days, system consisting of a series of implants, made of industry standard materials, with no new materials being introduced in the product, comparably sized, and indicated for the same uses.

Summary:

The Solana Surgical device and the predicate device have the same design characteristics and intended use. The new device is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 1 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Solana Surgical, LLC
% Bruce R. Lawrence, DPM
1828 Bailey Drive
Oceanside, CA 92056

Re: K090127

Trade/Device Name: Metatarsal Decompression Implant
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: II
Product Code: KWD
Dated: April 8, 2009
Received: April 10, 2009

Dear Dr. Lawrence:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

(240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a large initial "M" and a small "for" written below it.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090127
Device Name: Metatarsal Decompression Implant
Indications for Use:

The Solana Surgical LLC, Metatarsal Decompression Implant is intended for use as a hemi-arthroplasty implant for the first metatarsophalangeal joint, for the treatment of degenerative and post-traumatic arthritis, hallux valgus, hallux rigidus, and an unstable or painful metatarsophalangeal (MTP) joint.

The device is intended for single use to be used with bone cement.

Prescription Use x AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K090127